DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration D1354 B

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

December 30, 1997

WARNING LETTER
CHI-7-98

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Hector E. Izquierdo, President
Ventilatory Care Management
6330 Belmont Road
Downers Grove, Illinois 60516

Dear Mr. Izquierdo:

An inspection of your facility located at 6330 Belmont Road, Downers Grove, Illinois, was conducted by FDA investigator Mark I. Kaspar on November 25 and 26, 1997. The inspection determined that your firm manufactures Oxygen, USP, in liquid form. This medical gas is a drug as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). This inspection revealed your liquid oxygen is adulterated under the Act.

Your liquid oxygen is adulterated under Section 510(a)(2)(B) of the Act in that the methods used in, or the facilities or controls used for, its manufacturing, packing, holding, or shipping are not in conformance within the Current Good Manufacturing Practice Regulations (CGMPs) for drugs as specified in Title 21, Code of Federal Regulations, Parts 210 and 211, as follows:

1. You failed to assay the incoming liquid oxygen for strength after its receipt from the supplier and prior to filling the cryogenic home units. Additionally, you failed to maintain records to document the identity testing of the same incoming liquid oxygen once received from the supplier.

2. You failed to have an up-to-date written procedure that describes how your firm fills home cryogenic vessels from your [redacted] gallon storage tank.

3. You failed to ensure that all employees involved in the filling of liquid oxygen into home cryogenic vessels received adequate training in that process.

4. You failed to maintain records of the inspection of home cryogenic vessels prior to their being filled with liquid oxygen.

These findings were discussed with Brett Den Uyl, Director of Operations and Clinical Services, at the conclusion of the inspection. A copy of the FDA-483, List of Observations, which was given originally to Mr. Den Uyl on November 26, 1997, is enclosed.

The above identification of violations is not intended to be an all-inclusive listing of deficiencies at your firm. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all warning letters about drugs so they can take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions without further notice. These may include seizure and/or injunction. **This is your official notification that we expect all of your facilities to be in compliance.**

We have enclosed the latest copy of a speech given by our National Expert, Mr. Duane Sylvia, entitled "Fresh Air '96 - A Look at FDA's Medical Gas Requirements." This speech will assist you in understanding your responsibilities as a medical manufacturer. Pages 4-6 specifically cover testing of incoming liquid oxygen and cryogenic home vessels.

If you wish to obtain a copy of the Act [DHHS Publication No. (FDA) 93-1051], contact the Superintendent of Documents, Attn: New Orders, P.O. Box 371954, Pittsburgh, PA 15250-7954. Charge orders may be telephoned to the GPO Order Desk at (202) 512-1800 from 8:00am to 4:00pm Eastern time, Monday through Friday, or FAX'd to (202) 512-2233. You can also obtain these publications in Chicago by calling the Government Bookstore at (312) 353-5133. The Act is approximately $20 and the CFR is approximately $7.

You should notify this office in writing within 15 days of receipt of this letter regarding the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframe within which the corrections will be completed.

Your written response should be directed to the attention of Richard Harrison, Acting Compliance Officer.

Sincerely,

/S/

Raymond V. Mlecko
District Director

Enclosures

cc: Mr. Brett Den Uyl
Director of Operations & Clinical Services
Ventilatory Care Management
6330 Belmont Road
Downers Grove, IL 60516